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(54) Implantable multi-pole coaxial lead.

(57) A plurality of conductors (2_1, 2_2, 2_3, 2_4) are wound to a multi-pole helix. The conductors 2 are individually insulated by a first insulating material 3 (e.g. PTFE), and the insulated conductors 2 are embedded in and axially separated from each other by a second tube-formed insulating material 4 (e.g. silicone rubber). The inner opening of the tube comprises a helically wound stylet guide coil 5, possibly in the form of a multi-pole conductor arrangement.

The conductors 2 and 5 could be helically wound, multifilament wires.

Preferably, all helically wound arrangements in the lead are wound in the same direction so that the lead is stiff when rotating it in one direction and flexible when rotating it the other way.

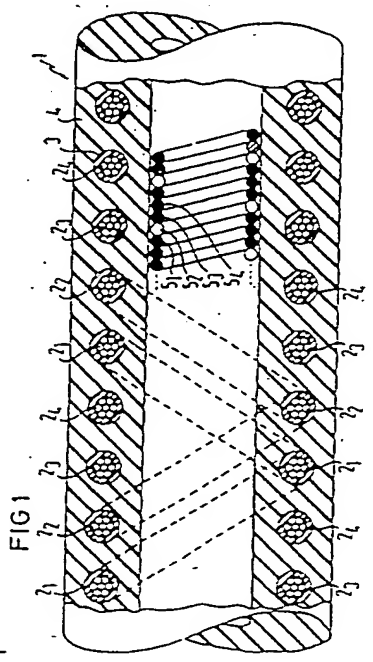

FIG 1

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Implantable multi-pole coaxial lead

The present invention relates to an implantable multi-pole coaxial lead or cable of the type suitable for use in an electrode arrangement for stimulating intracardiac tissue in a pacer system.

The demands on a multi-pole coaxial lead for use as part of an implanted electrode arrangement in i.e. heart pacemakers with a long life time are extremely high. A lead of this type must be i.e. body compatible, of low resistance to maintain energy consumption at a low level thereby increasing life time of pacemaker batteries, exhibit a high fatigue strength under repeated bending stresses, pliant in order to cause minimum disruptions to surrounding organs as well as stiff enough when pushed forward to enable an easy insertion at the clinic.

Moreover, these demands are at least in part contradicting as is obviously the case for pliant and low resistance requirements. In order to be pliant the conductors of the lead should essentially have a small diameter and in order to be of low resistance the conductors should have a great diameter.

The attempts to overcome these difficulties in the past are manifold. In contrast to a conventional coaxial lead DE-A-3 031 752 discloses a coaxial lead wherein the conductors are individually insulated and wound into a single multi-pole helix. Although the diameter of this lead is reduced in comparison to a conventional lead with an inner and an outer helix of conductors separated from another by an insulating sheath and the conductors also being surrounded at the exterior of the lead by a further insulating sheath, the multi-pole helix neccessarily has a steeper pitch and thus exhibits reduced flexibility. Further, the single insulating material requires a compromise between the electric properties and body compatibility for that material.

EP-A-92 798 presents a solution where the outer helix is a metal tape or tape shaped cord in order to reduce diameter and resistance while increasing flexibility.

A lead for i.e. catheters and electrical measurements in the medical field is examplified in DE-A-2 408 707 and comprises a multi-pole lead in which a multi-pole helix of axially separated conductors with a first insulating material is further insulated in such a way that the helix is comprised in the wall of a tube-formed second insulating material. The interior of the tube is a fluid conduit. Although this arrangement where the conductors and the first insulating material are embedded in the second insulating material enables a reduced diameter as well as good electrical insulating and body compatibility properties of this lead, the explicitly stated materials for the conductor, copper, and for the first insulating material, insulating paint, have however properties which make this lead unsuitable for implantation, especially intracardial implantation. The materials in a lead for intracardial implantation must withstand around 100.000 bendings a day, and consequently the lead must exhibit an extremely high fatigue strength. Further, if a stylet would be used at insertion, the walls of insulating material in the central opening of the lead could easily be penetrated.

It is an object of the present invention to provide an implantable multi-pole coaxial lead presenting an optimal compromise to the diverging requirements for stiffness, flexibility, fatigue strength and resistance discussed in the preceding paragraphs.

The above object is inventively achieved in the device defined in claim 1.

The lead in claim 1 essentially defining a helix of individually insulated conductors embedded in the wall of the lead tubing and where the inner opening of the tubing comprises a helically wound stylet guide coil is advantageous in that it exhibits reduced diameter, good electrical and body compatibility properties in combination with a stylet guide member protective against penetration.

Preferably, the stylet guide coil could comprise individually insulated conductors in a multi-pole arrangement to increase the versatility of the lead.

Preferably, to increase flexibility of the lead, at least one conductor is a wire and comprised of helically wound multiple filaments.

Preferably, in order to further improve lead properties at insertion all helixes in the lead are wound in the same, i.e. left or right hand direction. This preferable embodiment corresponds to the habit of the surgeons to insert the lead in a way where the forward direction of the lead includes helical movement of the surgeon's hand in one direction, and withdrawal of the lead includes a movement of the surgeon's hand in the opposite direction. As it is preferable that the lead is flexible at withdrawal from the fixation tissue and stiff when approaching the fixation tissue, and several attempts may be required before an optimal electrode fixation is achieved, it is of great importance that this is an intrinsic property of the lead irrespective of stylet function. This is achieved by arranging all helixes in the same direction, viz., for right handed surgeons the helixes should be wound in the left hand direction and for left handed surgeons the helixes should be wound in the right hand direction.

Other embodiments of the invention are di-

rected to e.g preferable combinations of conductor and insulating materials.

In order that the invention may be more readily understood reference will now be made to the accompanying drawings.

FIG 1 is an axial sectional view of a multi-pole coaxial lead constructed in accordance with the present invention illustrating a four-pole conductor arrangement embedded in an insulating tube of silicone rubber. The stylet guide coil is illustrated as a four-pole arrangement.

FIG 2 is a radial sectional view of a helically wound multi-filament conductor.

Refering now to the figures, an embodiment of the invention discloses a multi-pole lead 1 having outer helically wound conductors 2 in a four-pole arrangement 2_1, 2_2, 2_3, 2_4. The conductors 2 consist of multi-filament (e.g. refined steel) wire exhibiting high fatigue strength under repeated bending stress. The filaments are all wound in the same direction. The conductors are surrounded by a first insulating material 3 with good electric insulating properties, such as FEP (Fluorinated Ethylene Propylene) or PTFE (Polytetrafluorethylene). The conductors are embedded in a second insulating material 4 with good body compa tibility properties, e.g. silicone rubber such as silastic Q7-4840 produced by Dow Corning Company. A central opening in the tube-formed second insulating material exhibits a stylet guide coil 5 arranged as a multi-pole conductor arrangement 5_1, 5_2, 5_3, 5_4. The guide coil conductors may be comprised of MP 35 N, possibly in a multi-filament arrangement.

The conductors 2, 5 may be individually identified by e.g. coloured insulation material, possibly combined with an X-ray contrast medium. By way of example, the guide coil could have an inner diameter of about 0,5 mm and the lead could have an outer diameter of about 2,0 mm. The outer conductor helix is wound with a pitch of 2 to 4 mm, and the distance between the insulated conductors is around 0,2 mm. The tube-formed second insulating material, is produced in two steps, the first step comprising the extrusion of the inner part of the tube, and the second step comprising the extrusion of the outer part of the tube on the insulated outer conductors 2 wound on the inner part of the tube, so that the outer conductor helix is embedded in the integrated tube wall.

The described embodiment could be modified to comprise various pole arrangements of the conductors in the outer and in the guide coil helixes.

Reference list

1 multi-pole lead
2 conductor
2_1, 2_2, 2_3, 2_4 four-pole conductor arrangement
3 first insulating material
4 second insulating material
5 Stylet guide coil
5_1, 5_2, 5_3, 5_4 multi-pole conductor

Claims

1. A multi-pole coaxial lead for an electrode for stimulating body tissue having a plurality of conductors (2_1, 2_2, 2_3, 2_4) wound to a helix and each conductor being insulated by a first insulating material (3), the insulated conductors (2) being embedded in and axially separated from each other by a second, tube-formed, insulating material (4) **characterized in that** the inner opening of said second material comprises a helically wound stylet guide coil (5).

2. A lead according to claim 1, **characterized in that** at least one conductor (2) is a multifilament wire.

3. A lead according to claim 1 to 2, **characterized in that** the stylet guide coil (5) is at least in part of conducting material.

4. A lead according to claim 1 to 3,**characterized in that** the stylet guide coil (5) is a multi-pole arrangement of conductors.

5. A lead according to claim 1, 3 or 4, **characterized in that** the guide coil conducting material is a multi-filament wire.

6. A lead according to claim 2 or 5, **characterized in that** the filaments are helically wound.

7. A lead according to any preceeding claim **characterized in that** all helically wound arrangements in the lead are wound in the same direction.

8. A lead according to claim 1 to 7, **characterized in that** the first insulating material (3) is Fluorinated Ethylene Propylene (FEP) or Polytetrafluorethylene (PTFE) and that the second insulating material is silicone rubber.

9. A lead according to claim 1 to 8 in which the first insulating material (3) has an individual conductor identification.

10. A lead according to claim 9 in which said identification is an X-ray contrast medium, a colour or a combination thereof.

FIG 2

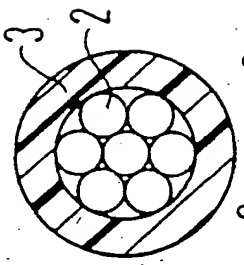
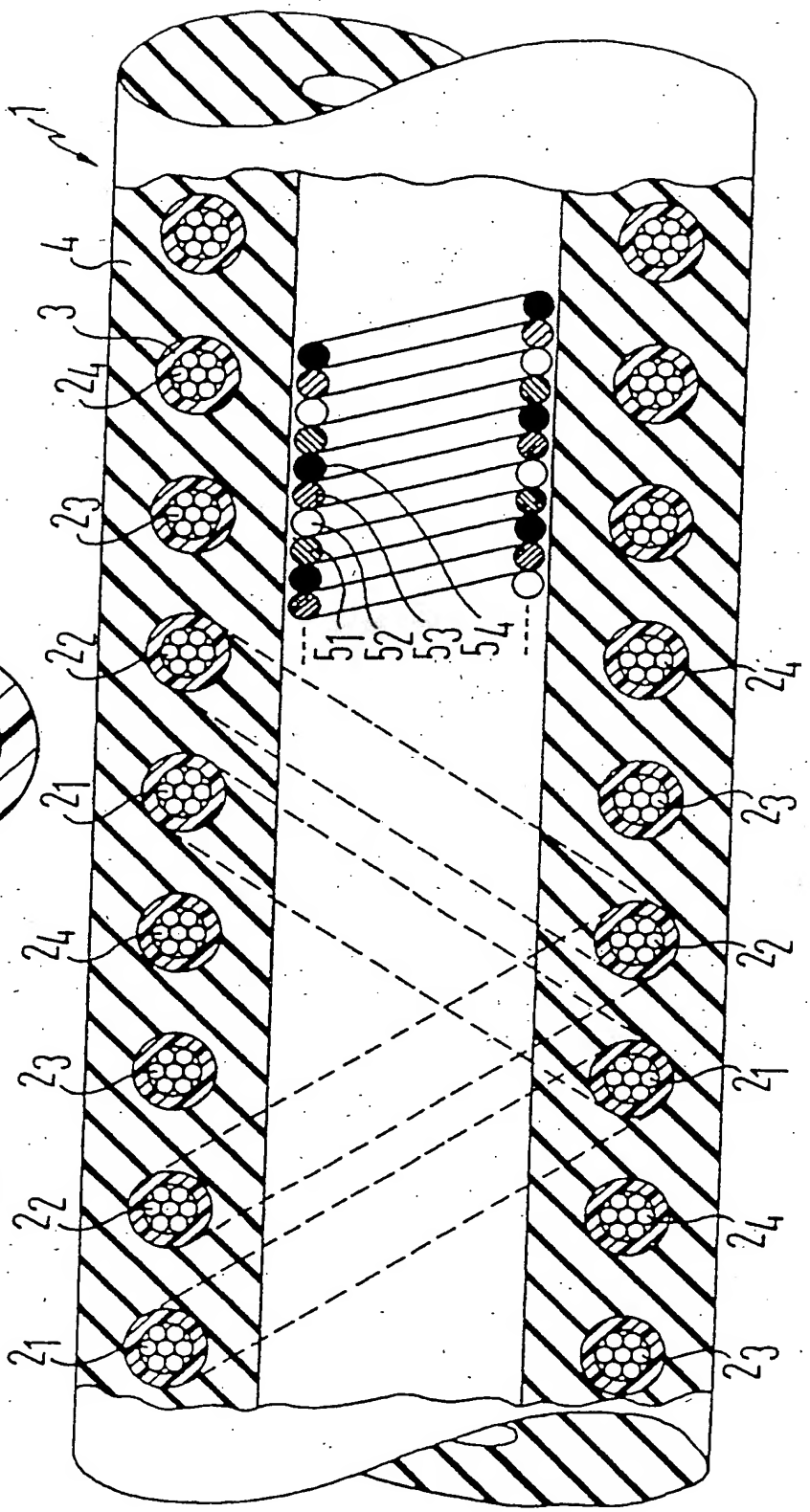


FIG 1



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EUROPEAN SEARCH REPORT

Application Number

EP 87 10 7895

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	EP-A-0 162 178 (INSTITUT STRAUMANN) * Page 7, lines 7-33; page 10, lines 28-34; page 19, line 25 - page 20, line 7; page 21, lines 16-25; figures 1,7,8 *	1-7	A 61 N 1/05
A	CH-A- 656 313 (INSTITUT STRAUMANN) * Page 3, lines 16-44; page 4, lines 1-23; page 5, lines 26-28 *	1,2,8	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)

A 61 N
A 61 B
H 01 B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	02-02-1988	LEMERCIER D.L.L.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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